SEP 2 0 2000

K000664

052

510(k) Summary

Submitter:	Baxter Healthcare Corporation CardioVascular Group 17221 Redhill Avenue Irvine, CA 92614-5686
Contact Person:	Paula A. Torrianni, Manager, Regulatory Affairs
Date Prepared:	February 25, 2000
Trade name:	*Vigilance* Continuous Cardiac Output/Continuous End Diastolic Volume (CCO/CEDV) Monitor *Vigilance* Continuous Cardiac Output/Oximetry/Continuous End Diastolic Volume (CCO/SvO_2/CEDV) Monitor
Classification Name:	Cardiac Output/Dual Oximeter/Ejection Fraction Computer Single-Function, Preprogrammed Diagnostic Computer (21 CFR 870.1435)
Predicate Devices:	*Vigilance* Continuous Cardiac Output (CCO) Monitor *Vigilance* Continuous Cardiac Output/Oximetry (CCO/SvO_2) Monitor REF-1™ Ejection Fraction/Cardiac Output Computer
Device Description:	The *Vigilance* CCO/CEDV and CCO/SvO_2/CEDV Monitors are microprocessor-based instruments which, when connected to a Baxter thermodilution catheter, measure cardiac output both continuously (CCO) and by the intermittent bolus (injectate) method (ICO). The *Vigilance* CCO/SvO_2/CEDV Monitor additionally measures mixed venous oxygen saturation. The monitors also continuously generate right ventricular ejection fraction (EF) and end diastolic volume (EDV).
Intended Use:	The *Vigilance* CCO/CEDV and CCO/SvO_2/CEDV Monitors are intended to measure both bolus/injectate and continuous cardiac output in addition to continuous right ventricular ejection fraction and end diastolic volume. The *Vigilance* CCO/SvO_2/CEDV Monitor is also intended to measure mixed venous oxygen saturation. These systems also calculate hemodynamic and oxygenation parameters.
Comparative Analysis:	The *Vigilance* CCO/CEDV and CCO/SvO_2/CEDV Monitors have been demonstrated to be as safe and effective as the predicate devices for their intended use.

Functional/Safety Testing:	The *Vigilance* CCO/CEDV and CCO/SvO_2/CEDV Monitors have successfully undergone functional and animal testing as well as software verification and validation, electrical safety and environmental testing. They have been shown to be equivalent to the predicate devices.
Conclusion:	The *Vigilance* CCO/CEDV and CCO/SvO_2/CEDV Monitors are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2000

Ms. Paula A. Torrianni
Baxter Healthcare Corporation
17221 Red Hill Avenue
P.O. Box 11150
Santa Ana, CA 92711-1150

Re: K000664
Vigilance CCO/CEDV and Vigilance CCO/SvO_2/CEDV Monitors
Regulatory Class: II (two)
Product Code: DXG
Dated: June 23, 2000
Received: June 26, 2000

Dear Ms. Torrianni:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000664

Device Name: *Vigilance* CCO/CEDV and *Vigilance* CCO/SvO_2/CEDV Monitors

Indications for Use:

The *Vigilance* CCO/CEDV and *Vigilance* CCO/SvO_2/CEDV Monitors are indicated for use in patients requiring monitoring of hemodynamic parameters, including cardiac output, mixed venous oxygenation, right ventricular ejection fraction, and end diastolic volume.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

(Per 21 CFR §801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K000664

(Optional Format 1-2-96)